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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,199	08/05/2003	Robert E. Johnson	3618/1/US	8286

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EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,199	JOHNSON ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *1-19,21-31 and 33-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,32 and 39-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/8/03,6/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-61 are pending.

2. Applicant's election with traverse of Group II, claims 20, 32 and 39-61 drawn to a high concentration modified antibody formulation in the reply filed on 8/7/06 is acknowledged.

Applicants traversed the restriction requirement based on that there is no serious search burden imposed. This is not found persuasive because the pending claims of each group from the original restriction are patentably distinct methods as referred in this restriction requirement. It is undue burden to search more than one invention. A prior art reads on a method for treating a disease with a TNF-α antibody differs from a prior art reads on method for production of a TNF-α antibody. The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-19, 21-31 and 33-38 are withdrawn from further consideration by the examiner 37CFR 1.142(b) as being drawn to a nonelected invention.

Claims 20, 32 and 39-61 are currently being examined.

3. Applicant's IDS filed 10/8/03 and 6/24/04 have been acknowledged.

4. Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

5. Claims 20 and 32 are objected to as being depended upon non-elected claims and should be written as independent claims.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 20, 39 and 47-53 are rejected under 35 U.S.C. 102(b) as being anticipated by the U.S. Pat. No. 6,267,958 (IDS reference) as is evidenced by the specification of instant application on p. 2.

The '958 patent teaches an antibody composition comprising a concentration of about 300 mg/ml in a diluent such as buffer at pH about 6 (col. 17, lines 1-15, claims 1-8 col. 9, lines 39-45, col. 14-15 overlapping paragraph, in particular) and the antibody composition encompasses a polyclonal antibody having conjugates (e.g. moiety, col. 10, lines 21-45, in particular).

The '958 patent further teaches that the antibody formulation is dialyzed prior to lyophilization (col. 27-28, overlapping paragraph, in particular).

In addition, the '958 patent teaches that the antibody formulation retains the physical and chemical stability (prevents aggregates) and it is useful for various methods of administration including subcutaneous administration (col. 2, lines 9-36, col. 9, lines 8-15, in particular).

As is evidenced in the instant specification on p.2, [006], the modified antibody encompasses any antibody having at least one "moiety" attached directly to the antibody or indirectly to the antibody via a linker. The disclosed moiety encompasses the referenced conjugates (col. 10, lines 21-45, in particular).

Claims 20, 52 and 53 are included in this rejection because the claimed invention is drawn to a reconstituted antibody formulation comprising a modified antibody and a buffer. The patentability of the product does not depend on its method of production. A formulation is the same formulation irrespective of how it is purified. Thus, prior art teachings anticipate the claimed invention.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 20, 32, 39-51 and 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO01/94585 (IDS reference, No.1) in view the U.S. Pat. No. 6,267,958 (IDS reference) as is evidenced by the specification of the instant application on p. 2.

The'585 publication teaches a modified antibody comprising nonproteinaceous polymer covalently attached to an antibody through a succinimide moiety linker, CDP 870 (p. 7-9, 41, Fig 13, abstract and claims 35-42, in particular), poly(ethyleneglycol)polymer, methoxypoly(ethyleneglycol)(p. 8, lines 5-15, in particular) and covalent linkage of methoxypoly(ethyleneglycol) polymers to a lysine residue via succinimide moiety (Fig 13, in particular).

The '585 publication does not teach a high antibody concentration formulation.

However, the '958 patent teaches a high antibody concentration formulation and has been discussed, supra. As is evidenced in the instant specification on p.2, [006], the modified antibody encompasses any antibody having at least one "moiety" attached directly to the antibody or indirectly to the antibody via a linker. The disclosed moiety encompasses the referenced conjugates (col. 10, lines 21-45, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to stabilize the modified CDP870 antibody as taught by the '585 publication with a high antibody concentration formulation as taught by the '958 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '958 patent teaches that the formulation comprising modified antibody and a buffer at pH 6 adds physical and chemical stability to any antibodies (prevents aggregation of antibody) and it is more useful for various methods of administration (col. 2, lines 9-36, col. 9, lines 8-15, in particular).

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 52, 53, 60 and 61 rejected under 35 U.S.C. 103(a) as being unpatentable over WO01/94585 (IDS reference, No.1) and U.S. Pat. No. 6,267,958 (IDS reference) as is evidenced by the specification of the instant application on p. 2, as applied to claims 39, 50, 54 and 58 above, and further in view of the U.S. Pat. 3,855,197.

The teachings of the '585 publication and the '958 patent have been discussed, supra.

The '585 publication and the '958 patent do not teach diafiltration and equilibrium dialysis as recited in claims 52, 53, 60 and 61.

However, the '197 patent teaches the diafiltration and equilibrium dialysis yield very pure and enriched proteins in purification steps (col. 5, lines 6-23, col. 6, lines 1-15, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to combine the diafiltration and equilibrium dialysis techniques as taught by the '197 patent to the high antibody concentration formulation containing the modified CDP870 as taught by the '958 patent and the'585 publication.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '197 patent teaches that the diafiltration and the equilibrium dialysis yield pure and enriched proteins in purification steps (col. 5, lines 6-23, col. 6, lines 1-15, in particular).

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 20, 32, 39-50 and 54-57 are provisionally rejected under the judicially created doctrine of double patenting over pending claims 1, 3-5, 7-12 and 29-32 of copending Application No. 10/634,581. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a modified antibody formulation in a buffer at pH about 4-6.5 and the antibody concentration is at about 300mg/ml. The modified antibody comprises an antibody fragment and nonproteinaceous polymer covalently linked to the antibody fragment through a linker comprising a succinimide moiety. The nonproteinaceous polymer includes polyethyleneglycol polymers. In addition, the specification of the 10/634,581 application

teaches the CDP870 as a preferred antibody (Example 1, p. 12 in the '581 application, in particular)

13. Claims 51-53 and 58-61 are rejected on the ground of provisional nonstatutory obviousness-type double patenting as being unpatentable over pending claims 1, 3-5, 7-12 and 29-32 of copending Application No. 10/634,581 in view of. U.S. Pat. No. 3,855,197.

The teachings of the '581 application has been discussed, supra.

The '581 application publication does not teach diafiltration and equilibrium.

However, the '197 patent teaches the diafiltration and equilibrium dialysis yield very pure and enriched proteins in purification steps (col. 5, lines 6-23, col. 6, lines 1-15, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to combine the diafiltration and equilibrium dialysis techniques as taught by the '197 patent to the high antibody concentration formulation containing the modified CDP870 as taught by the '581 application.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '197 patent teaches that the diafiltration and the equilibrium dialysis yield pure and enriched proteins in purification steps (col. 5, lines 6-23, col. 6, lines 1-15, in particular).

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. Claims 20, 32, 39-50 and 54-57 directed to an invention not patentably distinct from claims 1, 3-5, 7-12 and 29-32 of commonly assigned 10/634,581. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a modified antibody formulation in a buffer at pH about 4-6.5 and the antibody concentration is at about 300mg/ml. The modified antibody comprises an antibody fragment and nonproteinaceous polymer covalently linked to the antibody fragment through a linker

comprising a succinimide moiety. The nonproteinaceous polymer includes polyethyleneglycol polymers. In addition, the specification of the 10/634,581 application teaches the CDP870 as a preferred antibody (Example 1, in the '581 application, p. 12, in particular).

15. Claims 51-53 and 58-61 directed to an invention not patentably distinct from claims 1, 3-5, 7-12 and 29-32 of commonly assigned 10/634,581 in view of U.S. Pat. No. 3,855,197. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth above in section 13.

16. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending applications 10/634,581, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

17. No claim is allowable.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
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September 29, 2006

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